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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/821,025

Applicant(s)

BIJL ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/23/04 has been entered.

Claims 68-95 are being considered on the merits.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68-95 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay taken with Carduck *et al.*, Akimoto *et al.*, Casey *et al.* and Remington *et al.* for the reasons as stated in the last Office action and the further reasons below.

Barclay discloses a granule composition comprising extruded microorganisms, which are dead and non-disrupted. See, e.g., col. 12, lines 32-60. The referenced composition is prepared by the same process and is useful for the same purpose of providing omega-3 highly unsaturated fatty acids, for example, from unruptured cells by extraction (See, e.g., col. 13, lines 13-20). The process of extrusion results in a biomass that is granular and porous, as adequately demonstrated by Carduck (See, e.g., col. 4, last paragraph). Even though the microorganisms are alive rather than dead in the composition of Carduck, the properties of the product of Carduck are not substantially altered whether the yeasts are dead or alive. In this regard, Carduck is relied upon to adequately demonstrate that porous granules are produced by extrusion having the correct dimensions. Again, whether the cells are alive or dead does not materially alter the physical properties of the extruded composition of microbial cells, including the extraction of products yielded therefrom.

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The Barclay reference differs from the claimed invention in that the extruded granules contain microorganisms that are not bacteria or fungi, in the absence of specific compounds in these microorganisms and may differ in the size of the particles or granules as well as the percentage of pores. However, Akimoto *et al.* adequately demonstrate that *Mortierella*, a yeast, is known to contain polyunsaturated fatty acids such as arachidonic acid which can be extracted with a solvent (See, e.g., Table 1). In addition, the reference discloses that *Aspergillus* is also a suitable source of similar compounds. In addition, Casey *et al.* adequately demonstrate that *Pichia*, also a yeast, is known to contain tetraacetylsphingosine (TAPS) (See, e.g., page 3, lines 32 et seq.).

With respect to the specific content of dry matter and the specific sizes and percentage of porosity as claimed, it is apparent that these limitations are met by the composition of Barclay, but even if they are not, the selection of particle size for a dried extruded granular composition is within the skill of the ordinary artisan in this art, as adequately demonstrated by Remington *et al.* See, e.g., pages 1623-1627. In particular, the reference states that particle-size distribution can be controlled by varying the speed of rotation and drying temperature as well as by comminuting the granulation to the desired granule size after drying (page 1624, col. 2, last paragraph).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Barclay by selecting and drying bacteria or fungi that contain useful substance rather than algae to provide a dried extruded microbial granular product containing dead bacteria or fungi including *Pichia* comprising TAPS, as suggested by Casey *et al.* or *Mortierella* or *Aspergillus* comprising lipids as suggested by Akimoto *et al.*, for the expected benefits of providing a valuable dried granular product containing dead fungi or bacteria that is porous and which is stable and easy to handle and from which a chemical compound comprised by the cell is extractable through the pores. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching,

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suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all of the references are directed to microbial biomass products that are suitable ~~as suitable~~ as food and/or as a source for the extraction of proteins, lipids, vitamins, etc. from the microbial cells, which products include at least bacteria and fungi. Applicant has not demonstrated unexpected properties for the product produced. It is not apparent that the nature of the microorganism extruded materially affects the properties of the granule composition, since the biological products contained therein are substantially the same. From the teachings in the prior art, one of ordinary skill in the art would be motivated to select a microorganism containing a useful biological material, such as protein or oil, such as bacteria or fungi in view of the teachings of Akimoto *et al.* and Casey *et al.*.

Regarding Carduck, Applicant alleges that live and dead microorganisms are in “totally different fields” and that the person skilled in the art would not combine such references because the intended use of the composition is different is not persuasive. Applicant has not demonstrated with objective evidence that the properties of the dried extruded product of Carduck in the context of the instant invention are substantially altered whether the yeasts therein are dead or alive. Carduck teaches porous granules containing fungi produced by extrusion having the correct dimensions.

Akimoto *et al.* adequately demonstrates that *Mortierella*, a fungus, is known to contain polyunsaturated fatty acids such as arachidonic acid, (See, e.g., Table 1) and that *Aspergillus* also comprises useful compounds such as lipids and Casey *et al.* demonstrates that *Pichia*, also a yeast, is known to contain tetraacetylsphingosine (TAPS) which can be extracted with a solvent (See, e.g., page 3, lines 32 et seq.). One of ordinary skill in the art would be motivated to select such microorganisms to produce extruded granule compositions for the expected benefits of providing products having stability and ease of handling, particularly if the microbes are dead, as taught by Barclay.

Applicant's arguments regarding the irrelevance of Remington are noted. This reference is cited to demonstrate that the selection of particle size is within the skill of the ordinary artisan in this art, and in particular, that particle-size distribution can be controlled by varying the speed of rotation and drying temperature as well as by comminuting the granulation to the desired granule size after drying (page 1624, col. 2, last paragraph). In this regard, Applicant argues a process of extruding cells, while the invention as claimed is directed to a composition, i.e., “A

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granule composition comprising extruded microorganisms which are fungi or bacteria" wherein the granules are porous and have a certain size range.

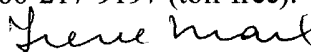
Applicant's arguments have failed to rebut the strong *prima facie* case of obviousness made out over the references. Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
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